

**FREDERICK MEMORIAL HEALTHCARE SYSTEM**

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May 25, 2007

BY FACSIMILE

David A. Neumann, Ph.D.
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Maryland Health Care Commission
4160 Patterson Avenue
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**Re: Comments on Draft Regulations COMAR 10.24.05(d) Research
Waiver Applications for Participation in the Atlantic Cardiovascular
Patient Outcomes Research Team Study of Non- Primary Percutaneous
Coronary Interventions Performed in Maryland Hospitals Without
On-Site Cardiac Surgery**

Dear Dr. Neumann:

Frederick Memorial Hospital (FMH) is delighted to have this opportunity to submit preliminary comments on the above-referenced regulation prior to its being proposed for adoption. As you know, FMH has recently received permission to offer primary percutaneous coronary interventions at its site, and believes the elective PCI -C-PORT II study and the waiver created by the proposed regulation, offer a great opportunity for improved cardiac care to the citizens of Frederick County. The FMH and Washington County Hospital Association (WCHA) approvals mark the first time that these advanced and necessary coronary interventions have been readily available to most of the population of the Western Maryland health planning area.¹ The research study into the efficacy and safety of elective percutaneous coronary interventions performed without on-site cardiac surgery promises to be extremely useful as research while providing significant benefits to the citizens of our county.

The geographic imbalance of advanced cardiac surgery services in Maryland is well known. The great majority of the state's open-heart surgery capacity, and the bulk of the existing primary C-PORT exemptions, are found in the Baltimore and Washington metropolitan areas. Five of the 10 hospitals in the state that can offer open-heart surgery are located inside the Baltimore beltway. Three OHS providers are located near or inside the Washington Beltway. The only open-heart surgery (OHS) provider in the Western Maryland HSA is located in Cumberland, Maryland and serves only the far western portions of Maryland, and Peninsula Regional Medical Center in Salisbury serves the eastern shore.

¹ The Commission's predecessor granted the only open-heart approval in Western Maryland to the hospitals in Cumberland, but there is no out migration from Frederick County to the far western portion of the state.

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The hospitals with permission to offer primary C-PORT are similarly disproportionately distributed – seven in the greater Baltimore region; four in metropolitan Washington, and the two recently granted waivers in Western Maryland. Subsequently, Mercy Hospital withdrew and a waiver was granted to Upper Chesapeake Medical Center, leaving 11 primary PCI providers in the two metropolitan areas and two in Western Maryland. The current imbalance of open heart surgery hospitals and primary PCI providers without on-site OHS services in the metropolitan Baltimore and Washington areas, coupled with the limitation to six providers and the eligibility rules found in proposed COMAR 10.24.05.03 presents a problem for FMH, which we believe must be addressed to ensure citizens of other areas of the State with this much needed service. Specific comments are given below.

COMAR 10.24.05.02C.

The proposed provision permits the Commission to grant a waiver from Policy 5.0 of COMAR 10.24.17.04E for no more than six hospitals without on-site cardiac surgery. At the outset, FMH believes that the limitation to six hospitals may be appropriate at the beginning of the research study, but may not be in the best interest of either the study or the residents of the State of Maryland over time, and wonders if that issue is subject to reconsideration at a later time..

COMAR 10.24.05.03B, Requirements to File Application.

The proposed eligibility rules create one set of requirements for the 11 hospitals in the Metropolitan Baltimore or Metropolitan Washington regional service area that have primary PCI waivers and different requirements for hospitals everywhere else in the state. We agree that the rule for hospitals in the Eastern Shore or Western Maryland regional service areas must necessarily differ, since the hospitals in the metropolitan areas have been operating for several years and FMH and WCHA did not receive permission to initiate their programs until the Commission meeting in March 2007.² The requirement for Western Maryland therefore states “at the time of the application, the hospital has a waiver to perform primary PCI, has provided PCI services for at least six-months, and has completed the minimum of eighteen primary PCI procedures.”

² There are no approved primary PCI waivers on either the Eastern Shore or in Southern Maryland at the present time.

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In its filing, FMH indicated that it anticipated opening its PCI program on or about January 1, 2008. Therefore, under these proposed rules, FMH would not be able to file an application for waiver until August 2008.

COMAR 10.24.05.03.C. Submission of Application.

There is a difference in the timing between Central Maryland/Washington Metropolitan areas and Western Maryland. As to the former, the Commission has indicated that it will publish a schedule in the Maryland Register for a single review of waiver applications. *COMAR 10.24.05.03C(1)*. A hospital in Western Maryland files written notice of intent to file an application for a waiver "no earlier than 30 days after the six-month anniversary of the initiation of the primary PCI services at the hospital." *COMAR 10.24.05.03C(2)(a)* If one of the two Western Maryland hospitals files under this provision, the other would have to file an application for waiver "thirty days after the filing of the notice specified in *COMAR 10.24.05.03C(2)(a)* or, if the Commission publishes a review schedule, according to that to be established review schedule." *COMAR 10.24.05.03C(2)(b)*

This different timing rule presents a potential problem for the Western Maryland hospitals. If either of the two Western Maryland hospitals were to "win the race" to be opened for six months and promptly files a waiver application within 30 days, it is not clear that the other hospital would be permitted to file because of the limitation contained in *COMAR 10.24.05.03.B (2)*. That is, if either FMH or WCHA had been opened for six-months and performed eighteen or more procedures several months ahead of the other hospital reaching the same milestone, the second hospital might not meet the eligibility to file rule laid out in *COMAR 10.24.05.03B(2)*. This would be a most unfortunate result that would prevent a full and fair consideration of the applications for waiver of hospitals in Western Maryland, while creating a race to open that may not be in the best interests of the hospitals or the populations they serve.

FMH believes the Commission should establish scheduled dates for submission of waiver application for the Western Maryland region that is set sufficiently in advance to allow the entities that are likely to be in a position to meet the criteria to file a waiver request..

FMH understands the benefits of requiring a hospital to demonstrate that it can provide primary PCI in a safe and effective manner prior to permitting it to extend into an

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elective PCI program. However, it is important that any hospital new to the primary PCI program establish its service with all the thought, preparation and care that can be afforded. A race to start up is entirely inconsistent with that process. For the Western Maryland area, FMH believes the scheduled filing dates should be published in the Maryland Register and set sufficiently in the future to allow both hospitals that have recently received primary PCI permission to meet the eligibility standard in accordance with the statements they made in their applications to obtain permission to operate primary PCI. Moreover, we suggest that the number of successful cases is a far more important indicator than simply time.

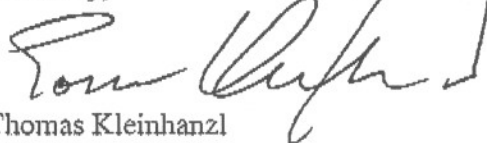
Setting a timetable in a published schedule eliminates the race to be first component of the proposed regulation. Requiring a greater number of successful cases consistent with a schedule designed to give the potential applicants time to prove their programs work in fact will give the Commission a tool to evaluate proposals.

COMAR 10.24.05.04A(3)(a)

FMH strongly supports the proposed language in COMAR 10.24.05.04A(3)(a), which notes that "An applicants potential to improve the geographic distribution of cardiovascular services" is one of the appropriate factors that the Commission may consider in approving a waiver. Certainly, geographic distribution and the availability of services are critical factors in statewide planning for advanced cardiac services that have not been major factors in the past, as evidenced by the geographic imbalance of such services in the State.

The Hospital appreciate this opportunity to present preliminary comments in advance of a formal release of the proposed regulation for comment, and would be pleased to offer further comments when the regulations are formally proposed. FMH applauds the benefits of the C-Port Study, and looks forward to the opportunity to file an application for waiver to permit offering these needed services to the citizens of Frederick County.

Sincerely,



Thomas Kleinhanzl
President and Chief Executive Officer
Frederick Memorial Hospital, Inc.

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TH/rlh

cc: Mr. James Williams (FMH)
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